DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 28 2004

SP 04P-0175/CP1

Intervet, Inc.
Attention: Ruth LaCrosse-Vernimb
Manager, Regulatory Compliance and QA - Pharmaceuticals
405 State Street
P.O. Box 318
Millsboro, DE 19966-9906

Dear Ms. Lacrosse-Vernimb:

In your Suitability Petition filed April 14, 2004, you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a change in strength from that of an approved new animal drug. The proposed pioneer product is Pharmacia and Upjohn's EAZI- BREED™ CIDR® (progesterone) Cattle Insert (NADA 141-200) which is intended for use in cattle for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, for advancement of first postpartum estrus in suckled beef cows, and for advancement of first pubertal estrus in replacement beef heifers.

Your proposed product differs from the pioneer product in strength. The proposed generic product is an insert, which can be administered intravaginally, as is the pioneer. The proposed generic product is intended to deliver the same amount of active ingredient per pound of body weight, and is intended for individual animal treatment, as is the pioneer.

Change in strength is one of the five variances in the pioneer product which can be considered through a Suitability Petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. We are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed generic product.

Your Suitability Petition is approved. Approval of the Suitability Petition does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA. Please include a copy of this letter in your generic application.

An *in vivo* bioequivalence study to demonstrate bioequivalence between the pioneer and the generic products will be required. We recommend that you submit protocols for our evaluation before initiating any studies. The *in vivo* bioequivalence study must indicate

2004P-0175 PAV 1

equal dosing between pioneer and generic products.

The pioneer product is protected by an exclusivity that expires on May 2, 2005, for the intra-vaginal insert route in cattle. It is also protected by an exclusivity that expires on July 29, 2006 for the use in synchronizing the return to estrus in lactating dairy cows which were inseminated during the proceeding estrus.

We will conduct a definitive labeling review when the ANADA for the proposed generic product is submitted to the Center. The generic labeling should be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences, such as manufacturer's tradename and other appropriate changes.

You may contact Dr. Lonnie W. Luther, Chief, Generic Animal Drug Team, at 301-827-8549, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,

Steven D. Vaughn DVM

Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine